Hyperfine Reports on Growing Evidence for the Use of Swoop® System Images in Stroke Diagnosis Presented at the 2025 International Stroke Conference

February 6, 2025

Two presentations at ISC build on a growing body of data demonstrating the value of AI-powered portable MR images in providing information to aid physicians in the diagnosis of acute ischemic stroke, including data from the ACTION PMR stroke study.

GUILFORD, Conn.--(BUSINESS WIRE)--Feb. 6, 2025-- Hyperfine, Inc. (Nasdaq: HYPR), the groundbreaking health technology company that has redefined brain imaging with the world's first FDA-cleared AI-powered portable magnetic resonance (MR) brain imaging system—the Swoop® system —today announced the presentation of *two studies* at the 2025 International Stroke Conference (ISC), which provide evidence supporting the value of AI-powered portable MRI in acute ischemic stroke triage and diagnosis. Notably, this includes patient data in the Acute Ischemic Stroke Detection with Portable MR (ACTION PMR) study.

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The AI-powered Swoop® portable MR brain imaging system. (Photo: Business Wire)

Ohio State University, an ACTION PMR site, presented its data* from the study showing that physicians were able to use Swoop® system images to diagnose 90 percent of acute infarcts seen on conventional high-field MRI—the standard of care—and also demonstrated DWI-FLAIR mismatch, a key method of identifying acute ischemic stroke. Researchers from Massachusetts General Hospital also presented data* on stroke detection, showing that images from the Swoop® system enabled accurate differentiation of stroke versus stroke mimics with strong agreement to high-field MRI, indicating the Swoop® system's value in evaluating patients with suspected stroke and transient ischemic attack.

The ACTION PMR study is a prospective, international, multi-site observational study that aims to examine the value and role of brain imaging with the Swoop® portable MR brain imaging system in acute ischemic stroke diagnosis and treatment. Enrollment in the study is complete with one hundred patients at four leading institutions in the US and Europe—the University at Buffalo, the University of Glasgow, Ohio State University Wexner Medical Center, and Massachusetts General Hospital. These patients enabled a direct comparison of stroke detection between portable MRI and the standard of care as a means to assess the utility of Swoop® system images in stroke detection.

ACTION PMR data has been presented at multiple leading conferences throughout the study progression, including the Radiological Society of North America (RSNA) and the European Society of Neuroradiology (ESNR). Taken together, data from patients in ACTION PMR has shown that physician diagnosis using AI-powered portable MRI images produced substantial agreement with physician diagnosis using standard-of-care imaging in detecting acute ischemic strokes. In addition, the Swoop® system showed faster time-to-scan compared to conventional MRI and good specificity in emergency stroke care.

Taylor Kimberly, MD, PhD, of Massachusetts General Hospital, the study's principal investigator, commented, "Since ACTION PMR launched in July 2023, my colleagues and I have seen very promising results indicating that portable, ultra-low-field MR imaging can be a valuable tool for stroke detection and triage. The demonstration of accurate lesion detection validates the feasibility of this technology as an accessible, scalable alternative to conventional imaging." He continued, "The improved time to imaging compared to conventional MRI could facilitate quicker decision-making in acute stroke management, which could lead to the implementation of more effective treatments and help to facilitate better patient outcomes."

Maria Sainz, Hyperfine, Inc. President and CEO, adds, "The ACTION PMR study shows that the Swoop system has the potential to activate a paradigm shift in stroke diagnosis and treatment all over the world. By combining cutting-edge AI with portability, we empower healthcare providers with critical diagnostic imaging that can change the course of treatment in acute care settings such as the emergency department. As we move forward with additional clinical studies, we are honored to work with distinguished clinical investigators and stroke advisors to gather further evidence on how the Swoop® system can make brain imaging faster and more accessible in emergency settings."

For more information about the Swoop® Portable MR Imaging® system, please visit hyperfine.io.

**Data available upon request.*

About the Swoop® Portable MR Imaging® System
The Swoop® Portable MR Imaging® system is U.S. Food and Drug Administration (FDA) cleared for brain imaging of patients of all ages. It is a portable, ultra-low-field magnetic resonance imaging device for producing images that display the internal structure of the head where full diagnostic examination is not clinically practical. When interpreted by a trained physician, these images provide information that can be useful in determining a diagnosis. The Swoop® system is also CE marked in the European Union and is UKCA marked certification in the United Kingdom. The Swoop® system is commercially available in a select number of international markets.

About Hyperfine, Inc.
Hyperfine, Inc. (Nasdaq: HYPR) is the groundbreaking health technology company that has redefined brain imaging with the Swoop® system—the first FDA-cleared, portable, ultra-low-field, magnetic resonance brain imaging system capable of providing imaging at multiple points of professional care. The mission of Hyperfine, Inc. is to revolutionize patient care globally through transformational, accessible, clinically relevant diagnostic imaging. Founded by Dr. Jonathan Rothberg in a technology-based incubator called 4Catalyzer, Hyperfine, Inc. scientists, engineers, and physicists developed the Swoop® system out of a passion for redefining brain imaging methodology and how clinicians can apply accessible diagnostic imaging to patient care. For more information, visit hyperfine.io.

Forward-Looking Statements
This press release includes “forward-looking statements” within the meaning of the “safe harbor” provisions of the Private Securities Litigation Reform Act of 1995. Actual results of Hyperfine, Inc. (the “Company”) may differ from its expectations, estimates and projections and consequently, you should not rely on these forward-looking statements as predictions of future events. Words such as “expect,” “estimate,” “project,” “budget,” “forecast,” “anticipate,” “intend,” “plan,” “may,” “will,” “could,” “should,” “believes,” “predicts,” “potential,” “continue,” and similar expressions (or the negative versions of such words or expressions) are intended to identify such forward-looking statements. These forward-looking statements include, without limitation, the Company’s goals and commercial plans, the benefits of the Company’s products and services, and the Company’s future performance and its ability to implement its strategy. These forward-looking statements involve significant risks and uncertainties that could cause the actual results to differ materially from the expected results. Most of these factors are outside of the Company’s control and are difficult to predict. Factors that may cause such differences include, but are not limited to: the success, cost and timing of the Company’s product development and commercialization activities, including the degree that the *Swoop*® system is accepted and used by healthcare professionals; the impact of COVID-19 on the Company’s business; the inability to maintain the listing of the Company’s Class A common stock on the Nasdaq; the Company’s inability to grow and manage growth profitably and retain its key employees; changes in applicable laws or regulations; the inability of the Company to raise financing in the future; the inability of the Company to obtain and maintain regulatory clearance or approval for its products, and any related restrictions and limitations of any cleared or approved product; the inability of the Company to identify, in-license or acquire additional technology; the inability of the Company to maintain its existing or future license, manufacturing, supply and distribution agreements and to obtain adequate supply of its products; the inability of the Company to compete with other companies currently marketing or engaged in the development of products and services that the Company is currently marketing or developing; the size and growth potential of the markets for the Company’s products and services, and its ability to serve those markets, either alone or in partnership with others; the pricing of the Company’s products and services and reimbursement for medical procedures conducted using the Company’s products and services; the Company’s estimates regarding expenses, revenue, capital requirements and needs for additional financing; the Company’s financial performance; and other risks and uncertainties indicated from time to time in Company’s filings with the Securities and Exchange Commission, including those under “Risk Factors” therein. The Company cautions readers that the foregoing list of factors is not exclusive and that readers should not place undue reliance upon any forward-looking statements, which speak only as of the date made. The Company does not undertake or accept any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements to reflect any change in its expectations or any change in events, conditions or circumstances on which any such statement is based.

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